

REMARKS/ARGUMENTS

Claims 1, 19, 34, 39, 57 and 58 have been revised to include the features of glutamic acid or glutamine at residue 250 in combination with leucine or phenylalanine at residue 428. Claims 8 and 24 have been revised to no longer include the feature of a modification at residue 428.

Claims 15-17 have been revised to be the counterparts of claims 2, 3, and 5, respectively, with dependency from claim 8. Applicants respectfully submit that with this revision, claims 15-17 may be rejoined with examined claim 8. Similarly, claims 31-33 have been revised to be the counterparts of claims 2, 3, and 5, respectively, with dependency from claim 24. Applicants respectfully submit that with this revision, claims 31-33 may be rejoined with examined claim 24. Additionally, claims 67-69 have been revised to be the counterparts of claims 2, 3, and 5, respectively, while maintaining their dependency from claim 58. Applicants respectfully submit that with these revision, claims 67-69 remain with claim 58.

Claims 35 and 40 have been canceled in favor of revised claims 34 and 39, respectively. Claims 36 and 41 have been revised to correct minor informalities.

Claims 43, 49 and 60 have been canceled in favor of claims 39, 8, and 58, respectively.

Claim 52 has been revised to update its dependency.

Claim 54 has been revised to feature specific sequences with substitutions at residue 250 as described in Table 1 of the instant application.

The above described revisions to the claims are all consistent with the election in response to Restriction and the requirement for election of species. They do not reflect any acquiescence to any rejection of record and are not made for any reason related to patentability. Applicants expressly reserve the right to pursue the subject matter of the claims, prior to the revisions, in a continuing application.

New claims 70-75 have been introduced with dependency from claim 8. Support for new claims 70-75 is present at least by the previously presented claims as indicated in the following chart:

| Previously presented claim | New claim(s) |
|----------------------------|--------------|
| 6 | 70 |
| 52 and 53 | 71 and 72 |
| 8, 9, 25 | 73 and 74 |
| 57 | 75 |

No new matter has been presented, and entry of the above revised claims is respectfully requested.

Information Disclosure Statement (IDS)

Enclosed herewith are forms PTO/SB/08A and PTO/SB/08B provided as a Supplemental IDS. Copies of documents AU, AV and AZ-BF in compliance with the requirements of 37 C.F.R. §1.98(a)(2) are enclosed. A copy of document AW was previously provided with copies of other documents and form PTO-1449 via a Communication mailed March 10, 2005. Unfortunately, that earlier filed form PTO-1449 contained an error in the indicated publication date for document AW. The inclusion of the correct information in the current form PTO/SB/08A provides compliance with 37 C.F.R. §1.98(b)(4).

The earlier filed form PTO-1449 also included a number of documents among AA to AN which were cited without complying with 37 C.F.R. §1.98(b)(4). Therefore, Applicants have included them in the instant form PTO/SB/08A to comply with that rule.

It is respectfully requested that the cited documents be expressly considered during the prosecution of this application, and the documents be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Interview Summary

Applicants thank Examiners Crowder and Gambel for the courtesy of a telephonic interview with the undersigned on October 10, 2006. During the interview, the undersigned pointed out the disclosure and guidance provided by the instant application with respect to the elected invention, comprising substitutions at positions 250 and 428 of the heavy chain constant region. Examples of the disclosure include Figures 11A and 11C as well as content in Example 6 of the application.

Additionally, the undersigned pointed out the more than additive effects observed with combinations of substitutions as shown in Tables 3-8 in Example 6. The undersigned then pointed out how the Martin et al. document does not disclose or suggest the particular substitutions or the greater than additive effect seen with their combination. Because the particular substitutions were not disclosed or suggested, the combination of Martin et al. with the Hinton et al. document was improper, as indicated by a review of claim 8's inclusion in the alleged rejection based on anticipation. Examiner Gambel generally agreed with respect to residue 250.

Restriction Requirement/Elected Invention

Applicants again confirm the election of Group I, claims 1-3, 5, 6, 8-12, 18-21, 23-28, 34-43, 49, 52, and 53.

Revised claims 15-17, 31-33, and 57, as well as new claims 70-75, are believed to correspond to the elected invention.

Applicants also acknowledge the Examiner's recognition of the standards for rejoinder as set forth at MPEP 821.04. Applicants respectfully point out that claims 58, 59, 61-64 and 67-69 are subject to those rejoinder rules.

Alleged Rejection Under 35 U.S.C. § 102

Claims 1, 8-12, 18, 19, 24-28, 34-43, 49, 52, and 53 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Martin et al. as evidenced by Hinton et al.

Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of anticipation is present.

As discussed during the telephonic interview on October 10, 2006, the Martin et al. document does not disclose or suggest i) the substitutions of glutamic acid or glutamine at residue 250, or ii) a combination of these alternative substitutions at residue 250 and leucine or phenylalanine at residue 428, of the heavy chain constant region in an antibody.

With respect to both of these deficiencies, Applicants point out that the lack of any guidance or suggestion as to the substitution at residue 250 renders the inclusion of Hinton et al. in the instant rejection misplaced. There is simply no disclosure regarding residue 250 in the Martin et al. document to provide basis for the assertion of Hinton et al. as showing an “inherent” teaching in Martin et al. This deficiency in the Martin et al. document also prevents a *prima facie* case of anticipation of the subject matter of claims 8, 24, or 54, each of which features substitution with either glutamic acid or glutamine at residue 250.

Additionally, Martin et al. also do not disclose or suggest that a combination of substitutions at residues 250 and 428, as featured in claims 1 and 9 for example, in a single molecule would result in more than additive effects in comparison to individual substitutions at the two residues. This is shown in at least Tables 3-5 of Example 6 in the instant application. For example, Table 3 shows that the relative binding of the T250E and M428F antibodies to be 3.5 and 3.2, respectively. But the combination of the two modifications results in an unexpected relative binding value of 15. Similar results are shown in Tables 4 and 5.

In light of the foregoing, Applicants respectfully submit that no *prima facie* case of anticipation is present, and so this rejection may be properly withdrawn.

Alleged Rejection Under 35 U.S.C. § 103

Claims 1-3, 5, 6, 20, 21, and 23 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Martin et al. (as discussed above) in view of Reff et al. and Ogata et al. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of obviousness is present.

As described above, Martin et al. do not teach or suggest the substitutions at residue 250 alone, or in combination with substitutions at residue 428, as featured in the revised claims. This deficiency is not remedied by either Reff et al. or Ogata et al. and so Applicants respectfully submit that no *prima facie* case of obviousness is possible because the claimed subject matter is neither taught nor suggested.

Additionally, and with respect to the claims directed to a combination of substitutions at residues 250 and 428, none of the cited documents, alone or in combination, teach or suggest the more than additive effects as shown in at least Tables 3-5 of Example 6 in the instant application.

In light of the foregoing, this rejection may be properly withdrawn.

Alleged Rejections Based on Obviousness-Type Double Patenting

Claims 1-3, 5, 8-10, 12, 19-21, 23-28, 34-43, 49, 50, and 53 were provisionally rejected as unpatentable over claims 1-8, 13, and 15 of commonly assigned, copending application 10/822,300. The statement of the rejection points out that a Terminal Disclaimer may be used to obviate this provisional rejection.

Applicants request that this provisional rejection be held in abeyance until the claims are otherwise allowable and the issue of obviousness-type double patenting is held as remaining.

Claims 1-3, 5, 8-10, 12, 18-21, 23-28, 34-43, 49, 50, and 53 were provisionally rejected as unpatentable over claims 1-5, 7-13, 15, and 17-19 of commonly assigned, copending application 10/966,673. The statement of the rejection points out that a Terminal Disclaimer may be used to obviate this provisional rejection.

Applicants request that this provisional rejection be held in abeyance until the claims are otherwise allowable and the issue of obviousness-type double patenting is held as remaining.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,



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Attachments
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